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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,094	02/09/2005	Boris P. Kovatchev	3053.128.US	4378

26474 7590 11/20/2008

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EXAMINER	
CLOW, LORI A	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
11/20/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,094	KOVATCHEV ET AL.	
	Examiner	Art Unit	
	Lori A. Clow	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-226* is/are pending in the application.

4a) Of the above claim(s) *40-111* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39 and 112-226* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response, filed 25 July 2008, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-226 are currently pending. Claims 40-111 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 28 November 2007.

Claims 1-39 and 112-226 are examined herein.

Claim Objections

Claims 11, step (a), step (c) and step (d) claim 15, step (c); claim 29, step (a), step (c), and step (d), (as well as the other instances present in the instant claim set) are objected to because of the following informalities: Each of the claims above, (as well as all other instances) recite glycosylated hemoglobin in terms of the acronym HbA_{1c}. Sometimes the "1c" is in a subscript format and sometimes it is not. For consistency of claims, please correct such that all instances are in the same format.

Claims 5, 23, and 119, for example, recite "wherein the preprocessing of the data for each patient comprise". This is grammatically incorrect and should be amended to recite "wherein the preprocessing of the data for each patient comprises".

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-18, 37, 38, 116-154, 175-214, and 221-226 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 37, 116-134, 175-194, and 221-226 are drawn to a system for evaluating the HbA_{1c} of a patient based on BG data collected over a first predetermined duration.

As stated in MPEP 2106, section IV, the claims will be evaluated for providing a practical application, if the claims are found to cover a judicial exception (*i.e.*, Law of Nature, Natural Phenomenon, or an Abstract Idea). In the instant case, the claims are drawn to an abstract idea and therefore must be evaluated further for providing a practical application of the judicial exception. A practical application is claimed if the claimed invention physically transforms an article or physical object to a different state or thing, or if the claimed invention otherwise produces a concrete, tangible, and useful result. In the instant case, a physical transformation of matter is not provided, as the instant claims merely provide steps within a system for *in silico* information manipulation. Therefore, none of said steps result in a physical transformation of matter such that the whole of the claim is statutory.

As such, the claims must be further evaluated for providing a practical application that produces a concrete, tangible and useful result. The focus is not on the steps taken to achieve a particular result, but rather the final result achieved by the claimed invention. A claim may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. communicated

to a user), and useful (i.e. a specific and substantial). In the instant case the step of "validat[ing] the estimate via sample selection criteria" does not provide a tangible result that is useful to one skilled in the art. Rather, those claim embodiments merely encompass *in silico* results with no specific output. The tangible requirement does require that the claim must recite more that a 101 judicial exception, in that the process claim must set forth a practical application of that 101 judicial exception to produce a real-world result. *Benson*, 409 U.S. at 71-72, 175 USPQ at 676-77 (invention ineligible because no "substantial practical application."). In the instant case, no real-world result is set forth, as the results could merely reside *in silico*.

In regard to claim 38, the claims are drawn to a "computer program product comprising a computer usable medium". The instant Specification discloses that a "computer usable medium" include signals. Therefore the instant claim reads on transitory propagating signals which are not proper patentable subject matter because they do not fit within any of the four statutory categories of invention (*In re Nuijten*, Fed. Cir. 2007).

In addition, claims 1-18, 135-154, and 195-214 are non-statutory because they also read on abstract ideas. The prohibition on patenting abstract ideas has two distinct aspects: (1) when an abstract concept has no claimed practical application, it is not patentable; (2) while an abstract concept may have a practical application, a claim reciting an algorithm or abstract idea can state statutory subject matter only if it is embodied in, operates on, transforms, or otherwise is tied to another class of statutory subject matter under 35 U.S.C. §101 (i.e. a machine, manufacture, or composition of matter). (*Gottschalk v. Benson*, 409 U.S. 63, 175 USPQ 673, 1972) (*In re Bilski,* Fed. Cir. 2008).

Claims 1-18, 135-154, and 195-214 are not so tied to another statutory class of invention because the **method** steps that are critical to the invention are "not limited to any particular apparatus or machinery." Claim limitations directed to obtaining or outputting data using an apparatus or machine are considered insignificant pre-solution and post-solution activity.

Response to Applicant's Arguments

Applicant argues that "the claims have been amended" and that "the results are outputted to a user", thereby providing a concrete, tangible, and useful result.

This is not persuasive, as claims 37, 116-134, 175-194, and 221-226 still do not recite an output or display, as stated above. In terms of claims 1-18, 38, 135-154, and 195-214, the rejections are necessitated by the recent decision in *In re Bilski*.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-39 and 112-226 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 19, 37, 38, 135, 155, 195, 215, and 221 (and claims dependent therefrom) recite "preparing the data for estimating HbA_{1c} using a predetermined sequence of mathematical formulas defined as: pre-processing of the data; estimating HbA_{1c} by applying at least one of the four predetermined formulas to said data and validation of the estimate via sample selection

criteria". It is unclear as to how a mathematical formula can be defined by the said steps above. How is a formula defined as, for instance, "pre-processing" without any parameters of how to "pre-process"? No formulas definitions, parameters, symbols, are set forth such that the claim is clear. Clarification is requested.

Claims 19, 38, 135, 155, 195, 215, and 221 recite, "a method for evaluating the glycosylated hemoglobin (HbA_{1c}) of a patient based on blood glucose (BG) data collected over a first predetermined duration" in the preamble of the claims. However, in the body of the claims, no such limitations where BG levels are actually obtained are recited. Therefore it is unclear as to what about the BG data the HbA_{1c} data is based upon. Clarification is requested.

Claim 5, 6, 23, 24, 119, 120, 139, 140, 159, 160, 179, 180, 199, 200, 219, 220, 225, and 226 recite, "wherein the preprocessing of the data for each patient comprise[s]". There is insufficient antecedent basis in the claim for "each patient" as only "a patient" is recited in the independent claims. Clarification is requested.

Claim 39 recites, "the computer program product of claim 38, wherein said computer program logic further comprises the steps of claim 11". It is unclear as to what steps of claim 11 the logic comprises. Is it one step, some steps, or all steps of claim 11? Clarification is requested.

Conclusion

No claims are allowed.

The outstanding rejections under 35 USC 102(b) over Cox and over Kovatchev are hereby withdrawn in view of Applicant's arguments.

The following prior art made of record and not relied upon is considered pertinent to applicant's disclosure: 7,025,425 (March 2006) which claims priority to WO 01/72208 (October 2001). These do not qualify as prior art under 102(e) because they are not "by another".

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

November 19, 2008
/Lori A. Clow/
Primary Examiner, Art Unit 1631